

CLAIM AMENDMENTS:

This listing of claims will replace all prior versions and listings of claims in the application:

1. (original) A formulation of amlodipine maleate where the formulation comprises a lubricant that does not contain alkaline-earth metal ions.
2. (original) The formulation of claim 1, where the alkaline-earth metal ion is magnesium.
3. (original) The formulation of claim 1, where the alkaline-earth metal ion is calcium.
4. (original) A formulation of amlodipine maleate comprising:
a therapeutically effective amount of amlodipine maleate,
a binder,
a diluent,
a disintegrant, and
a lubricant that does not contain magnesium.
5. (original) The formulation of claim 4, where the lubricant is selected from the group consisting of colloidal silicon dioxide, powdered cellulose, starch, glyceryl monostearate, glyceryl palmitostearate, hydrogenated castor oil, hydrogenated vegetable oil, mineral oil, polyethylene glycol, sodium benzoate, sodium lauryl sulfate, sodium stearyl fumarate,

stearic acid, macrogol 6000, dimeticone, stearic acid, and talcum.

6. (original) The formulation of claim 5, where the lubricant is selected from the group consisting of sodium stearyl fumarate, dimeticone, macrogol 6000, hydrogenated castor oil, and stearic acid.
7. (original) The formulation of claim 6, where the lubricant is hydrogenated castor oil.
8. (original) The formulation of claim 6, where the lubricant is hydrogenated castor oil in combination with another lubricant.
9. (original) The formulation of claim 8, where the other lubricant is talcum.
10. (currently amended) The formulation of claim 7, where the pH of the formulation is about 5.1 when measured as an aqueous slurry.
11. (original) The formulation of claim 7, where the formulation comprises less than 0.5% amlodipine aspartate.
12. (original) The formulation of claim 7, where the formulation comprises less than 0.5% amlodipine aspartate after storage at 40°C. and 75% relative humidity for one month.
13. (original) The formulation of claim 4, where the formulation comprises less than

0.5% amlodipine aspartate.

14. (original) The formulation of claim 4, where the formulation comprises less than 3% amlodipine aspartate after storage at 100°C. for 24 hours.

15. (original) The formulation of claim 4, where the formulation comprises less than 0.5% amlodipine aspartate after storage at 40°C. and 75% relative humidity for one month.

16. (currently amended) The formulation of claim 4, where the pH of the formulation is about 5.0 to 5.4 when measured as an aqueous slurry.

17. (currently amended) The formulation of claim 16, where the pH of the formulation is about 5.1 when measured as an aqueous slurry.

18. (original) The formulation of claim 4, where the binder is selected from the group consisting of acacia, alginic acid, carbomer, carboxymethylcellulose sodium, dextrin, ethyl cellulose, gelatin, guar gum, hydrogenated vegetable oil, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, liquid glucose, maltodextrin, methylcellulose, polymethacrylates, povidone, pregelatinized starch, sodium alginate, microcrystalline cellulose, modified cellulose, and starch.

19. (original) The formulation of claim 18, where the binder is selected from the group consisting of microcrystalline cellulose, modified celluloses, and povidone.

20. (original) The formulation of claim 4, where the diluent is selected from the group consisting of calcium hydrogen phosphate (CaHPO_4), anhydrous; lactose; and mannitol.

21. (original) The formulation of claim 4, where the disintegrant is selected from the group consisting of alginic acid, carboxymethylcellulose calcium, carboxymethylcellulose sodium, croscarmellose sodium, crospovidone, guar gum, methyl cellulose, microcrystalline cellulose, polacrillin potassium, powdered cellulose, pregelatinized starch, sodium alginate, sodium starch glycolate type A, sodium starch glycolate B, and starch.

22. (currently amended) The formulation of claim 21, ~~further~~ where the disintegrant is selected from the group consisting of sodium starch glycollate (type A), sodium starch glycollate (type B), and crospovidone.

23. (original) A formulation of amlodipine maleate comprising:
a therapeutically effective amount of amlodipine maleate
microcrystalline cellulose
calcium hydrogen phosphate (CaHPO_4), anhydrous
sodium starch glycollate (type B)
a lubricant that does not contain magnesium.

24. (original) The formulation of claim 23, where the formulation comprises less than 0.5% amlodipine aspartate.

25. (original) The formulation of claim 23, where the formulation comprises less than 3% amlodipine aspartate after storage at 100°C. for 24 hours.

26. (original) The formulation of claim 23, where the formulation comprises less than 0.5% amlodipine aspartate after storage at 40°C. and 75% relative humidity for one month.

27. (original) A formulation of amlodipine maleate comprising, by weight:

amlodipine maleate	about 2%-4%%
microcrystalline cellulose	about 40%-70%
calcium hydrogen phosphate (CaHPO ₄), anhydrous	about 25%-50%
sodium starch glycollate (type B)	about 1%-3%
a lubricant that does not contain magnesium	about 0.5%-7%.

28. (original) The formulation of claim 27, where the lubricant is two or more different lubricants that together represent about 0.5%-7% of the formulation, by weight.

29. (original) The formulation of claim 27, where the lubricant is selected from the group consisting of colloidal silicon dioxide, powdered cellulose, starch, glyceryl monostearate, glyceryl palmitostearate, hydrogenated castor oil, hydrogenated vegetable oil, mineral oil, polyethylene glycol, sodium benzoate, sodium lauryl sulfate, sodium stearyl fumarate, stearic acid, macrogol 6000, dimeticone, stearic acid, and talcum.

30. (original) The formulation of claim 29, where the lubricant is selected from the group consisting of sodium stearyl fumarate, dimeticone, macrogol 6000, hydrogenated castor oil, and stearic acid.

31. (original) The formulation of claim 30, where the lubricant is hydrogenated castor oil.

32. (original) The formulation of claim 30, where the lubricant is hydrogenated castor oil in combination with another lubricant.

33. (original) The formulation of claim 32, where the other lubricant is talcum.

34. (currently amended) The formulation of claim 31, where the pH of the formulation is about 5.1 when measured as an aqueous slurry.

35. (currently amended) A formulation of amlodipine maleate comprising, by weight:

amlodipine maleate	3.21%
microcrystalline cellulose	59.79-63.79%
calcium hydrogen phosphate (CaHPO ₄), anhydrous	30.00%
sodium starch glycollate (type B)	2-4%
a lubricant that does not contain magnesium-	1-7%.

36. (original) The formulation of claim 35, where the lubricant is selected from the group consisting of colloidal silicon dioxide, powdered cellulose, starch, glyceryl monostearate,

glyceryl palmitostearate, hydrogenated castor oil, hydrogenated vegetable oil, mineral oil, polyethylene glycol, sodium benzoate, sodium lauryl sulfate, sodium stearyl fumarate, stearic acid, macrogol 6000, dimeticone, stearic acid, and talcum.

37. (original) The formulation of claim 36, where the lubricant is selected from the group consisting of sodium stearyl fumarate, dimeticone, macrogol 6000, hydrogenated castor oil, and stearic acid.

38. (original) The formulation of claim 37, where the lubricant is hydrogenated castor oil.

39. (original) The formulation of claim 35, where the lubricant is two or more different lubricants that together represent about 0.5%-7% of the formulation, by weight.

40. (original) The formulation of claim 39, where the lubricant is hydrogenated castor oil in combination with another lubricant.

41. (original) The formulation of claim 40, where the other lubricant is talcum.

42. (currently amended) The formulation of claim 38, where the pH of the formulation is about 5.1 when measured as an aqueous slurry.

43. (original) A method of making a formulation of amlodipine maleate where the method comprises combining:

a therapeutically effective amount of amlodipine maleate

a diluent

a binder

a disintegrant

a lubricant that does not contain magnesium

where the resulting formulation of amlodipine maleate formed by so combining contains less than 0.5% amlodipine aspartate.

44. (original) The method of claim 43, where the formulation comprises less than 3% amlodipine aspartate after storage at 100°C. for 24 hours.

45. (original) The method of claim 43, where the formulation comprises less than 0.5% amlodipine aspartate after storage at 40°C. and 75% relative humidity for one month.

46. (currently amended) The ~~formulation~~ method of claim 43, where the lubricant is two or more different lubricants that together represent about 0.5%-7% of the formulation, by weight.

47. (currently amended) The ~~formulation~~ method of claim 43, where the lubricant is selected from the group consisting of colloidal silicon dioxide, powdered cellulose, starch, glyceryl monostearate, glyceryl palmitostearate, hydrogenated castor oil, hydrogenated vegetable oil, mineral oil, polyethylene glycol, sodium benzoate, sodium lauryl sulfate, sodium stearyl fumarate, stearic acid, macrogol 6000, dimeticone, stearic acid, and talcum.

48. (currently amended) The ~~formulation~~ method of claim 47, where the lubricant is selected from the group consisting of sodium stearyl fumarate, dimeticone, macrogol 6000, hydrogenated castor oil, and stearic acid.

49. (currently amended) The ~~formulation~~ method of claim 48, where the lubricant is hydrogenated castor oil.

50. (currently amended) The ~~formulation~~ method of claim 43, where the lubricant is hydrogenated castor oil in combination with another lubricant.

51. (currently amended) The ~~formulation~~ method of claim 50, where the other lubricant is talcum.

52. (currently amended) The ~~formulation~~ method of claim 49, where the pH of the formulation is about 5.1 when measured as an aqueous slurry.

53. (original) A method of treating and/or preventing hypertension, angina, or heart failure comprising administering to a patient in need thereof a therapeutically effective amount of a pharmaceutical composition comprising:

amlodipine maleate,

a diluent,

a binder,

a disintegrant, and

a lubricant that does not contain magnesium,
where the pharmaceutical composition comprises less than 0.5% amlodipine aspartate.

54. (new) The formulation of claim 1, where the pH of the formulation is about 5.0,
about 5.1, about 5.2, or about 5.3 when measured as an aqueous slurry.

55. (new) The formulation of claim 54, where the pH is about 5.1.

56. (new) The formulation of claim 4, where the pH of the formulation is about 5.0,
about 5.1, about 5.2, or about 5.3 when measured as an aqueous slurry.

57. (new) The formulation of claim 56, where the pH is about 5.1.

58. (new) The formulation of claim 23, where the pH of the formulation is about 5.0,
about 5.1, about 5.2, or about 5.3 when measured as an aqueous slurry.

59. (new) The formulation of claim 58, where the pH is about 5.1.

60. (new) The formulation of claim 27, where the pH of the formulation is about 5.0,
about 5.1, about 5.2, or about 5.3 when measured as an aqueous slurry.

61. (new) The formulation of claim 60, where the pH is about 5.1.

62. (new) The formulation of claim 35, where the pH of the formulation is about 5.0, about 5.1, about 5.2, or about 5.3 when measured as an aqueous slurry.

63. (new) The formulation of claim 62, where the pH is about 5.1.

64. (new) The method of claim 43, where the pH of the formulation is about 5.0, about 5.1, about 5.2, or about 5.3 when measured as an aqueous slurry.

65. (new) The method of claim 64, where the pH is about 5.1.

66. (new) The method of claim 53, where the pH of the formulation is about 5.0, about 5.1, about 5.2, or about 5.3 when measured as an aqueous slurry.

67. (new) The method of claim 66, where the pH is about 5.1.